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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/622,452 | 10/31/2000 | David B. Weiner | UPAP-0404 | 6483 |

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| EXAMINER | |
|---|---|
| BECKERLEG, ANNE M | |
| ART UNIT | PAPER NUMBER |
| 1632 | 8 |

DATE MAILED: 03/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/622,452 | WEINER ET AL. | |
| | Examiner | Art Unit | |
| | Anne M Beckerleg | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

**Election/Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, and 33-37, drawn to plasmids, vaccines, and nucleic acids encoding an immunogen and an immunomodulating protein, and methods of using said compositions, classified in classes 435 and 514, subclasses 320.1 and 44.

II. Claims 31-32, drawn to a live attenuated pathogen encoding an immunomodulating protein, classified in class 435, subclass 252.3.

III. Claims 33-37, drawn to methods of inducing an immune response comprising administering a protein immunogen and a protein immunomodulatory protein, classified in class 514, subclass 2.

IV. Claims 33-37, drawn to methods of inducing an immune response comprising administering a protein immunogen and a nucleic acid encoding an immunomodulatory protein, classified in class 514, subclasses 2 and 44.

V. Claims 33-37, drawn to methods of inducing an immune response comprising administering a nucleic acid encoding an immunogen and a protein immunomodulatory protein, classified in class 514, subclasses 2 and 44.

VI. Claims 38-39, drawn to pharmaceutical compositions comprising and antibody and methods of using said antibody, classified in classes 530 and 424, subclasses 387.1 and 130.1.

The inventions are distinct, each from the other because of the following reasons:

1)Inventions I, III, IV, and V are distinct in that the elements of the compositions differ substantially each from the other in physical and biological properties and particularly in modes of operation. Nucleic acids, which include plasmids and viral vectors, do not share the same biological properties as proteins, are not made using the same reagents or methods, and have substantially different biological activities both in vitro and in vivo. In addition, the physical properties of an immunogen or immunomodulatory molecule substantially affect the function and activity of the molecules both in individual cells and in larger organisms such as mammals. For instance, a protein immunogen must be taken up by an antigen presenting cell by phagocytosis or receptor mediated endocytosis and then processed and presented for immune stimulation. In contrast, a nucleic acid encoding an immunogen expresses the protein directly in the cell such that the protein has direct access to the ER and MHC class I molecules. An immunomodulatory molecule likewise may have different activities based on whether it is expressed by a nucleic acid from within a cell and presented on a membrane surface, or administered as a soluble protein. In addition, proteins versus nucleic acids behave differently in vivo. Proteins are affected by their half-life under various physiological conditions and their clearance rate from tissue or blood. Nucleic acids on the other hand must locate and infect or transfect target cells prior to protein expression.

2)Inventions I, III, IV and V are distinct from invention II in that a live attenuated pathogen is substantially different from nucleic acids, viral vector, or proteins in structure, physical properties, and biological activities.

3) Inventions I-V are distinct from invention III in that nucleic acids, proteins, and live pathogens are substantially different from antibodies in structure, physical properties, and biological activities. Further, the antibodies of the instant invention do not require the disclosed proteins or nucleic acids for their preparation or for their use in the disclosed methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of nucleic acids which encode an immunogen and/or immunomodulatory protein in claimed inventions I, IV and V:

a) plasmid vector

b) viral vector

c) a linear nucleic acid.

If inventions I, IV or V are elected, the applicant is required under 35 U.S.C. 121 to elect a single disclosed species from a)-c) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23-27, 29, 30, and 33-37 are generic.

This application contains claims directed to the following patentably distinct species of immunomodulatory proteins in all of inventions I-VI:

d) MCP-1

e) MIP-1 alpha

f) MIP-1 beta

g) IL-8

h) RANTES

I) L-selectin

j) P-selectin

k) CD34

l) GlyCAM-1

m) MadCAM-1

n) LFA-1

o) M-CSF

p) G-CSF

q) IL-4

r) Mutant forms of IL-18

s) CD40

t) CD40 Ligand

u) Vascular growth factor

v) IL-7

w) Nerve growth factor

x) VEGF

y) Fas

z) TNF receptor

aa) FLT

bb) Apo-1

cc) p55

dd) WS-1

ee) DR3

ff) TRAMP

gg) Apo-3

hh) AIR

ii) LARD

jj) NGRF

kk) DR4

ll) DR5

mm) KILLER

nn) TRAIL-R2

oo) TRICK2

pp) DR6

qq) Caspace ICE

Applicant is advised that a response to this requirement must include an identification of the species that is elected from the list comprising d)-qq) above, consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Currently, claims 1-3, 5-15, 17-25, 27-36, and 38-39 are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Beckerleg

A.M.S. BECKERLEG
PATENT EXAMINER